

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re: BAIR HUGGER FORCED AIR  
WARMING PRODUCTS LIABILITY  
LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To: All Actions

**PLAINTIFFS' OBJECTION TO  
MAGISTRATE JUDGE'S DENIAL  
OF PLAINTIFFS' MOTION TO  
OVERRULE VITAHEAT'S  
RELEVANCY OBJECTION**

**INTRODUCTION**

Plaintiffs respectfully submit this objection to Magistrate Judge Noel's Order<sup>1</sup> denying Plaintiffs' motion to overrule third party VitaHeat Medical, LLC's ("VitaHEAT"), relevancy objection.

Discovery continues to reveal alarming facts about safety hazards of Bair Hugger warming. From proof of internal contamination to disruption of airflow caused by the device, Plaintiffs have gathered extensive evidence Bair Hugger is causing infections. Until a few months ago, however, Defendants produced little to no evidence regarding VitaHEAT. Defendants had no relationship to VitaHEAT at the start of this litigation or during the initial phases of discovery. That changed in late 2016, when 3M reached an agreement to be the exclusive distributor of VitaHEAT's UB3 in the United States. The design of the UB3 emphasizes conductive and radiant heating, warming patients without circulating air.

Soon after learning 3M had acquired exclusive distribution rights to UB3, Plaintiffs subpoenaed VitaHEAT for documents. Despite having made numerous

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<sup>1</sup> See Doc. #249.

attempts to obtain discovery on HotDog, a similar device which features a conductive heating component, Blackwell Burke P.A., on behalf of VitaHEAT, objected to Plaintiffs' requests under the guise that designs featuring conductive heat are irrelevant to this case. Plaintiffs moved to overrule VitaHEAT's relevancy objection given the permissive standard of Rule 26(b)(1), along with the irreconcilability of Blackwell Burke's position when objecting to discovery versus seeking it. Indeed, Defendants previously told the Court "if Plaintiffs identify [a conductive device] as a supposed reasonable safer alternative product to the Bair Hugger system, then this discovery will be at the core of this case."<sup>2</sup> Defendants nonetheless flipped positions and opposed Plaintiffs' motion, burying in a footnote they had been "incorrect" to seek "HotDog-related documents."<sup>3</sup> Based on the declaration of Mr. Van Duren, VitaHEAT and Defendants argued UB3 was not an alternative design to Bair Hugger because Bair Hugger uses convection instead of conduction to warm patients.

Although L.R. 7.1(b)(3) precluded Plaintiffs from responding to those misrepresentations, the Magistrate Judge relied on Defendants' equally flawed argument and found that "a conductive patient warming device and a convective patient warming device are substantially different products."<sup>4</sup> By making this premature factual finding, the Magistrate Judge ignored the permissive standard of Rule 26(b)(1), disregarded the allegations in the Master Complaint, and incorrectly resolved a fact-intensive inquiry which nearly all courts reserve for summary judgment or trial. Because the Magistrate

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<sup>2</sup> Dkt. 130 at \*37.

<sup>3</sup> Dkt. 236 at \*4 n.2.

<sup>4</sup> Dkt. 249 at \*2.

Judge clearly erred as a matter of fact and law, Plaintiffs must respectfully object pursuant to L.R. 72.2.

## ARGUMENT

### **I. The Permissive Standard of Rule 26(b)(1) Governs this Discovery Dispute.**

Federal Rule of Civil Procedure 26(b)(1) states “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” *Orduno v. Pietrzak*, 2016 WL 5853723, at \*2 (D.Minn. 2016). The threshold requirement of discoverability is met “if the information sought is relevant to the subject matter involved in the pending action.” *Id.* at \*3. This Court broadly construes “relevancy” to mean “any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.” *Coleman v. Nat’l Life Ins. Co.*, No. 13-CV-2536 (JNE/FLN), 2014 WL 5860425, at \*2 (D.Minn. 2014)(emphasis added).

### **II. Plaintiffs Satisfy the Threshold Requirement of Relevancy.**

Contrary to the Magistrate Judge’s Order, discovery as to UB3 could bear on issues in this litigation. The Master Complaint alleges Defendants marketed Bair Hugger as safe in orthopedic surgeries despite knowledge of the risks of convective warming elements compared to conductive designs.<sup>5</sup> Allegations in the Master Long Form Complaint include the availability of “airflow-free warming,” which neither “increases bacterial contamination” nor “interrupts laminar airflow.”<sup>6</sup> Plaintiffs predicated Count II

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<sup>5</sup> E.g., Dkt. 97 ¶¶ 114–15.

<sup>6</sup> *Id.* at ¶¶ 61, 95.

of the Master Complaint on the fact that “safer alternative designs existed for the Bair Hugger, including airflow-free warming.”<sup>7</sup> In some instances, Plaintiffs must prove a reasonable alternative design. Plaintiffs’ discovery requests regarding “airflow-free” devices like UB3 are reasonably calculated to lead to the discovery of admissible evidence.<sup>8</sup> *Kuennen v. Wright Tech.*, 2015 WL 795032, at \*4 (N.D.Iowa 2015) (“Given the broad scope of relevancy in the discovery context . . . evidence regarding alternative designs is relevant to both Plaintiffs’ claims and Defendant’s defense.”).

In the *In re: Mentor Corp. MDL*, plaintiffs alleged defective design claims against the manufacturer of Obtape. 2010 WL 234797, at \*1 (M.D.Ga. 2010). After plaintiffs subpoenaed Ethicon, a third-party manufacturer of a different product called “TVT,” which allegedly provided an alternative design to Obtape, Ethicon moved to quash claiming the discovery was “not relevant.” *Id.* The MDL court denied the motion under Rule 26. *Id.* at \*1–3. In fact, according to Defendants in this case, “[t]he court quickly moved past the issue of relevance” because “Mentor had claimed [in its 510(k) application] its product was the substantial equivalent of Ethicon’s TVT.”<sup>9</sup> *Id.*

So too here. Just as plaintiffs in *In re: Mentor* sought discovery from a third-party manufacturer of a different medical device (TVT) that allegedly provided a safer alternative design to the subject device (Obtape), Plaintiffs here seek discovery from

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<sup>7</sup> *Id.* at ¶ 95.

<sup>8</sup> Defendants raised the same argument in moving to compel discovery on HotDog. Dkt. 152 at \*5. The Court denied the motion only because Plaintiffs had not yet claimed HotDog was an alternative design. Dkt. 148 at \*3. That is clearly not the case as to the UB3, however, given Plaintiffs’ representations herein.

<sup>9</sup> Dkt. 236 at \*14.

VitaHEAT, the manufacturer of another patient-warming device (UB3) that provides a safer alternative design to the subject device (Bair Hugger). Just as the third-party manufacturer in *In re: Mentor* argued nonparty discovery regarding a medical device was not relevant, VitaHEAT and Defendants argue here discovery as to the UB3 has no relevance, either. And just as VitaHEAT and Defendants admit the court in *In re: Mentor* “quickly moved past” the relevancy objections to plaintiffs’ discovery requests based on the fact that the FDA determined the two devices were “substantially equivalent,” this Court should follow suit: The FDA has already determined that the UB3, HotDog, and Bair Hugger are “substantially equivalent” devices even though the former devices use conduction and radiation design elements while Bair Hugger uses conduction, convection, and radiation to accomplish the identical goal of operative patient warming.<sup>10</sup>

**A. The Magistrate Judge erred as a matter of fact in denying the motion.**

Respectfully, the Magistrate Judge’s finding that UB3 and Bair Hugger are “substantially different products” runs headlong into the “substantial equivalence” of these devices. Devices are substantially equivalent when they have the same intended use and technological characteristics. The FDA cleared both UB3 and Bair Hugger as “Thermal Regulation Systems.” and found HotDog is “substantially equivalent” to Bair Hugger, and UB3 is “substantially equivalent” to Hot Dog. Accordingly, discovery concerning UB3 is surely relevant to claims of a potential alternative design to Bair Hugger. *See Mentor Corp.*, 2010 WL 234797, at \*3; *see also Cerner Corp. v. Visicu*,

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<sup>10</sup> *See* Dkt. 221-17 at \*6 (establishing UB3 is substantially equivalent to HotDog); *see also* Ex. A (establishing HotDog is substantially equivalent to Bair Hugger).

2011 WL 27577, at \*7 (W.D. Mo. 2011) (“An FDA decision that a device is substantially equivalent to a predicate device . . . means that they have a similar category of technological characteristics.”).

The Magistrate Judge disregarded other facts as well in determining UB3 and Bair Hugger are substantially different products. Consistent with the 510(k) filings for Bair Hugger, Defendants do not market it as a “forced-air warming” device. 3M’s website simply calls it a “warming unit.” The same applies to UB3. In each case, minimal emphasis is placed on the *method* by which the device warms patients. These marketing claims closely cohere with Defendants’ internal statements. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

Further still, a plethora of peer-reviewed studies directly compare conductive patient warming devices to Bair Hugger. In one such study, a longtime member of 3M’s Advisory Board refers to the conductive device as an “alternative” to Bair Hugger. *See Sessler, A Randomized Comparison of Intraoperative PerfecTemp and FAW During*

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<sup>11</sup> *E.g.*, Dkt. 221-4.

<sup>12</sup> *Id.* (emphasis added).

<sup>13</sup> *Id.* (emphasis added).

*Open Abdominal Surgery*, ANESTHESIA & ANALGESIA, 2011 Nov. 113(5):1076–81. To be sure, this national expert in normothermia was not comparing “apples” to “oranges.”

After all, Bair Hugger and UB3 do not use “fundamentally different types of technology.”<sup>14</sup> The day after Magistrate Judge’s Order, Plaintiffs deposed Mr. Van Duren, who testified on behalf of Defendants as a Rule 30(b)(6) witness that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]<sup>16</sup> This testimony vitiates the declaration he filed in support of Defendants’ opposition, in which he averred Bair Hugger is exclusively a “convective warming system.”<sup>17</sup> Moreover, in stark contrast to the 30(b)(6) testimony that Bair Hugger uses convection, conduction and radiation, his declaration states that “UB3’s conductive warming technology cannot be incorporated into the Bair Hugger.”<sup>18</sup> Since Defendants’ opposition hinged on these inaccuracies and fell far outside the four corners of the Master Complaint, the Magistrate Judge unknowingly erred in finding at this early stage of the litigation that “a conductive patient warming device and a convective patient warming device are substantially different products.”<sup>19</sup>

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<sup>14</sup> Dkt. 249 at \*2.

<sup>15</sup> Dkt. 268 at 134:25-135:5.

<sup>16</sup> *Id.* at 161:2-162:8.

<sup>17</sup> Dkt. 238 at \*2.

<sup>18</sup> *Id.* at \*3.

<sup>19</sup> Dkt. 249 at \*2.

On these facts, the Magistrate Judge should have allowed discovery concerning UB3 and waited until expert discovery and/or summary judgment to determine whether the devices are “substantially equivalent,” or “substantially different.” The Restatement (Third) of Torts provides Plaintiffs with “the opportunity to conduct reasonable discovery so as to ascertain whether an alternative design is practical.”<sup>20</sup> What’s more, neither one of the cases cited in the Order resolved as a mere discovery matter whether one product constituted an alternative design to another.<sup>21</sup>

In *Burks v. Abbott Labs.*, plaintiffs brought a design defect claim against the manufacturer of a powdered formula. 2010 WL 1576779, at \*3 (D.Minn. 2010). The defendants moved to dismiss on the ground that liquid formula was not an alternative design because it was an “altogether different product.” *Id.* at \*4. Judge Tunheim understood the concern but refrained from resolving the matter: “Given that defendants’ distinguishing facts fall outside the four corners of the [complaint], . . . this issue may be more appropriately resolved at summary judgment.” *Id.* The same held true in *Caterpillar, Inc. v. Shears*—the only other case cited in the Order. 911 S.W.2d 379, 384 (Tex. 1995) (ruling on alternative design issues after expert testimony and appeal of jury verdict).

Because the ultimate determination of whether one product constitutes an alternative design to another depends on the factual record—a record which can only be developed through the very third-party discovery Plaintiffs seek - it’s no wonder nearly

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<sup>20</sup> Restatement (Third) of Torts, §2, cmt. f.

<sup>21</sup> *Id.* at \*2–3.



all the cases cited by Defendants reserved the question for summary judgment or trial.<sup>22</sup> See, e.g., *Kimball v. R.J. Reynolds Tobacco Co.*, 2006 WL 1148506, at \*3 (W.D.Wash. 2006) (declaring that “the jury must decide” whether a product is an alternative design). Whether one medical device “is an entirely separate, discrete product” from another device “is a question of fact and/or for experts.” See, e.g., *Khan v. Karl Storz Endoscopy-Am., Inc.*, 2016 WL 4260784, at \*4 (D.N.J. 2016).

The same conclusion applies here. See *Security Nat’l Bank v. Abbott Labs.*, 2012 WL 327863, at \*10 (N.D.Iowa 2012) (“Defendant conveniently omits that [Burks] . . . went on to state that the issue may be more appropriately resolved at summary judgment.”). Tellingly, Defendants recognize the need for “expert evidence.”<sup>23</sup> The Magistrate Judge thus erred in making a premature finding that UB3 and Bair Hugger are substantially different products. *Edeh v. Equifax Info. Servs.*, 919 F. Supp. 2d 1006, 1017 (D.Minn. 2013) (Ericksen J. vacating Noel J.’s order pursuant to L.R. 72.2).

#### **B. The Magistrate Judge erred as a matter of law in denying the motion.**

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<sup>22</sup> *Hosford v. BRK Brands*, 2016 WL 4417256 (Ala. 2016); *Tersigni v. Wyeth*, 817 F.3d 364 (1st Cir. 2016); *Theriot v. Danek*, 168 F.3d 253 (5th Cir. 1999); *Hilaire v. DeWalt*, 54 F. Supp. 3d 223 (E.D.N.Y. 2014); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895 (E.D. Va. 2010); *Brockert v. Wyeth*, 287 S.W.3d 760 (Tex. App. 2009); *McCarthy v. Danek*, 65 F. Supp. 2d 410 (E.D.La. 1999); *Michael v. Wyeth*, 2011 WL 2150112 (W.D.W.Va. 2011); *Pinello v. Andreas Co.*, 2011 WL 1302223 (N.D.N.Y. 2011). Defendants also cited a few decisions granting motions to dismiss, but all those cases are inapposite. E.g., *Bertini v. Smith & Nephew*, 2013 WL 6332684, at \*2–4 (E.D.N.Y. 2013) (conclusory allegations).

<sup>23</sup> Dkt. 236 at \*5.

The Magistrate Judge also erred in concluding UB3 is not a “reasonable, safer, alternative to Bair Hugger.”<sup>24</sup> The Restatement (Third) of Torts provides “other products already available on the market [that] serve the same or very similar function at lower risk and at comparable costs . . . may serve as reasonable alternatives.”

Indeed, our courts routinely recognize “a safer design alternative [may be] implemented in other products.” *Block v. Toyota Motor Corp.*, 5 F. Supp. 3d 1047, 1067 (D.Minn. 2014); *see also Hoppe v. Midwest Conveyor Co.*, 485 F.2d 1196, 1202 n.3 (8th Cir. 1973).

In *Oldenburg v. Gymboree Corp.*, plaintiff brought a design defect claim against the manufacturer of a cotton children’s dress. 2013 WL 6196970, at \*1 (D.Minn. 2013). The defendant moved for summary judgment, arguing there was “no design defect because no safer alternative allegedly existed.” *Id.* at \*3. Citing expert evidence of “several less dangerous alternatives,” such as [clothes] “using one hundred percent nylon or polyester,” Judge Nelson held “such evidence might permit a jury to conclude that [the child’s] predominantly cotton, non-flame retardant dress was defective.” *Id.* at \*3-4. The fact that alternative designs used different fabrics held no weight; ergo, the fact that UB3 uses conduction and radiation while Bair Hugger uses conduction, convection, and radiation does not matter here, either.

*Security Nat’l Bank* is also on point. 2012 WL 327863, at \*9–11. In rejecting the defendants’ argument that liquid formula was not an alternative design to powdered formula, the court noted the absence of controlling precedent requiring a “magic line of

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<sup>24</sup> Dkt. 249 at \*2.

demarcation whereby suggested alterations constitute an alternative product rather than an alternative design.” *Id.* at \*10. “[T]o say a proposed alternative creates an alternate product rather than an alternate design is to say the proposed alternative cannot fulfill the function of the initial product.” *See id.*

Plaintiffs respectfully submit this Court should likewise refuse to draw a “magic line” between UB3 and Bair Hugger.<sup>25</sup> Given the similar indications for use and technological characteristics, along with Defendants’ marketing claims and scientific studies comparing these devices, the FDA has already determined UB3, HotDog, and Bair Hugger are among a family of “substantially equivalent” devices.<sup>26</sup> Unlike other methods of normothermia treatment, which range from fluid warming and ultraviolet treatment to humidification and passive insulation, the UB3 and Bair Hugger both use blankets to actively warm surgical patients. *See id.* \*10 n.6 (“The measure of similarity of the two products is inexorably related to the purposes for which they are used.”). Put simply, the end result is always active patient warming, even if UB3 uses conduction and radiation, while Bair Hugger uses conduction, convection, and radiation to accomplish the identical purpose. *See* Cupp, *Defining the Boundaries of “Alternative Design” Under the Restatement (Third) of Torts*, 63 TENN. L. REV. 329, 363 (1996) (“Similarity in

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<sup>25</sup> *Johnson v. Ethicon*, 2016 WL 7379009, at \*4 (S.D.W.Va. 2016) (denying summary judgment because a “natural alternative” to synthetic mesh could be alternative design); *Newman v. McNeil*, 2013 WL 7217197, at \*12 (N.D.Ill. 2013) (allowing drug with different chemicals and indications to constitute alternative design); *Sisk v. Abbott Labs.*, 2012 WL 3155586, at \*5 (W.D.N.C. 2012) (whether two products are “entirely different” is a “question of fact”); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 661 (E.D.Pa. 2012) (allowing expert testimony on whether different drugs could be alternatives).

<sup>26</sup> *See supra* note 10.

function is perhaps the most obvious factor for consideration in determining whether a comparison of products is fair.”).

None of the cases cited by VitaHEAT or Defendants change that undisputed fact. *See, e.g., Massa v. Genentech*, 2012 WL 956192, at \*1,7 (S.D.Tex. 2012) (“conventional [skin] treatments,” including topical agents and ultraviolet therapy, were “substantially different” than “biologics medications”); *Tersigni*, 817 F.3d at 365 (“other, safer methods of weight loss,” including exercise or diet, were substantially different than weight loss drug); *Theriot*, 168 F.3d at 255 (“neck braces” were substantially different than “pedicle screws”).

Nor does the Magistrate Judge’s reliance on the differences between a motorcycle and a four-wheeled vehicle dispose of the issue.<sup>27</sup> The essential characteristic of a motorcycle – two wheels – is lost by “adding two additional wheels and a cab.” *Caterpillar*, 911 S.W.2d at 385. After all, “[t]o add two wheels to a motorcycle would create a fundamentally different product and destroy the product’s distinct utility in the eyes of any potential consumer.” *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1017 (Mass. 2013). Not so here. UB3 and Bair Hugger serve the same goal of active warming of surgical patients and accomplish that goal through the same method of blanket warming. The fact that Bair Hugger uses convection, conduction, and radiation to warm patients, while UB3 uses only conduction and radiation to do so, does not render them “fundamentally different products,” let alone destroy the “distinct utility” of the products. *Id.* Why else would 3M distribute UB3 in tandem with Bair Hugger? So while “a line of

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<sup>27</sup> Dkt. 249 at \*3.

demarcation [between substantially different devices] may prove practicable in some rare instances, this is not one of them.” *Security Nat’l Bank*, 2012 WL 327863, at \*10.

At the end of the day, 3M acquired exclusive rights to distribute UB3, a patient-warming device which is just as effective but much less risky than blowing dirty air onto patients. That allegation, combined with the facts *supra*, proves the relevancy of discovery regarding UB3. *See Mentor Corp.*, at \*3; *see also Std. Fire Ins. Co. v. Broan Nutone*, 2008 WL 5560882, at \*6 (S.D.Miss. 2008) (“A competitor’s contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative.”). Because the Magistrate Judge erred as a matter of fact and law in concluding that UB3 is not an alternative design to Bair Hugger, this Court should vacate the March 6 Order. *See, e.g., Edeh*, 919 F. Supp. 2d at 1017.

### CONCLUSION

As counsel for VitaHEAT and Defendants have argued: “Discovery under the Federal Rules of Civil Procedure is permissive, authorizing parties to obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.”<sup>28</sup> Since UB3 is “substantially equivalent” to Bair Hugger, it is not a “substantially different product.” The March 6 Order prevents Plaintiffs from conducting reasonable discovery to prove their asserted alternative design claims. Plaintiffs respectfully object to the March 6<sup>th</sup> Order.

Respectfully submitted,

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<sup>28</sup> Dkt. 130 at \*14.

Dated: March 20, 2017

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